

REMARKS

Upon entry of the following amendments, claims 1-33 are pending in the present application. Claims 1-33 stand rejected. Claim 35 is newly added. Applicants have amended claims 1 and 8 - 16. The amendments and new claim are supported in the application as originally filed, for example in paragraphs 5, 11, and 12, among other places. No new matter has been added. Applicants respectfully request reconsideration in view of the following remarks.

Claim Rejections – 35 U.S.C. 102, 35 U.S.C. 103

Claims 1-4, 7-13 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,334,185 to Giesy et al. ("Giesy"). Claims 5, 6, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy as a matter of design choice. Claims 10 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,814,072 to Bonutti et al. ("Bonutti"). Applicants traverse these rejections for at least the reasons set forth below.

A claim is not anticipated or rendered obvious if each and every element of the claim is not found, either expressly or inherently, in the prior art references. See MPEP 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants' Claim 1 teaches a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle, a shaft having proximal and distal ends and attached to the handle at the proximal end, the distal end having a curved section and the proximal end having a substantially straight section, a pusher tube slideably fitted over the shaft and extending from the handle distally along the substantially straight section of the proximal end of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push an implant into the anatomical site.

Giesy discusses a device including a flexible sheath 22 slidably mounted upon a needle 20 and connected to a thumb piece 24. The needle of Giesy's device includes a notch 46 which

is operable to mate with a loop 44 attached to an implant 40. Giesy describes coupling an implant to the device by extending the sheath over the notch of the needle in order to lockingly engage the loop with the notch. After the device is locked, the implant is inserted into the patient.

The mechanism for removing an implant from Giesy's device involves actuating the thumb piece to slide the sheath back and expose the notch of the needle and then applying lateral forces to the device in order to disengage the loop from the notch. No mechanism is disclosed in Giesy for pushing an implant into a patient other than the exertion of the operator. Giesy does not teach or suggest a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push an implant into the anatomical site.

The Examiner stated that:

"Giesy teaches delivery device for delivering an implant to anatomical site in a body of a patient, the device comprising: a handle (12), a shaft having proximal and distal ends (20) and attached to the handle at the proximal end (20a), a pusher tube (22) slidably fitted over the shaft and extending from the handle distally along a portion of the shaft, and a pushing mechanism (24) operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant (40) to an anatomical site." (Office Action, page 4)

Applicants respectfully disagree with the Examiner's characterization of Giesy's device. The Examiner refers to the sheath 22 of Giesy as a pusher tube and button 24 as a pushing mechanism, but Giesy's sheath is applied to reinforce the coupling between Giesy's device and an implant and not to push the implant into the patient. Giesy does not teach or suggest a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push an implant into the anatomical site.

With regard to claim 19, Applicants further disagree with the Examiner's characterization of Giesy. In particular, the Examiner has stated that the item 40 of Giesy is a "sling (40) assembly," when in fact item 40 is a "catheter." See Giesy, col. 7, ln 6 et seq. The distinction between a "sling assembly" and a "catheter" is well understood in the medical device field and,

accordingly, traverse the rejection. Bonutti discloses a suture anchor inserter comprising a shaft with an inner member and an outer member, but the shaft of Bonutti's device is substantially straight with no curved sections. Neither Giesy nor Bonutti suggests a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising, a handle, a shaft having proximal and distal ends and attached to the handle at the proximal end, the distal end having a curved section and the proximal end having a substantially straight section, a pusher tube slideably fitted over the shaft and extending from the handle distally along the substantially straight section of the proximal end of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push an implant into the anatomical site. Accordingly, amended claims 1 and 10 and any claims that depend thereon are not anticipated by or rendered obvious by Giesy or Bonutti, and Applicants respectfully request withdrawal of the rejections.

Claim Rejections – 35 U.S.C. 103

Claims 20-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,960,160 to Browning ("Browning") in view of U.S. Patent No. 5,324,306 to Makower et al. ("Makower"). Applicants traverse the rejection for at least the reasons set forth below.

Browning discusses using a urethral support suspended between two soft tissue anchors. Browning does not teach or suggest the use of a pusher tube for delivering a surgical implant to a site in the body.

Makower discloses a surgical instrument for use in intravascular catheterization procedures. Makower defines his instrument as a puncture seal device for stemming the flow of blood from a punctured blood vessel.

The examiner states, without evidence or support from the references, that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Browning with a pusher tube mechanism as taught by Makower." Office Action, page 3.

Applicants respectfully disagree and assert that neither Browning nor Makower teaches or suggests the combination of their inventions to produce the system or methods of claims 10, 25, and 32. The Examiner must point to a teaching or suggestion to make the combination, or a motivation to do so in the knowledge generally available to one of ordinary skill in the art, but the Examiner has provided no such evidence.

Browning relates to the field of urinary incontinence treatments, and Makower relates to the field of intravascular catheterization procedures. These two disclosures apply to two different human diseases afflicting entirely different anatomical areas of a patient, and just because they apply generally to the treatment of human maladies is not a suggestion to combine their teachings. The Examiner has provided no evidence or suggestion of a motivation to combine the references and, accordingly, the rejection is improper.

As far as Applicants can discern, the Examiner has merely relied on the Applicants' claims for a suggestion to include claim elements together, and this hindsight rejection is improper. MPEP 2141 II. (C), "The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention."

CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.

Applicants believe no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 18-1945, Order No. MIY-P01-024 from which the undersigned is authorized to draw.

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Respectfully submitted,

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